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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,091	06/20/2005	Wenping Wu	10377.204-US	7525
25908 7590 03/05/2007 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT 1652	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/540,091

Applicant(s)

WU ET AL.

Examiner

Iqbal H. Chowdhury, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) 25-31, 33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a 371 of PCT/DK03/00914.

Claims 23-34 are currently pending in the instant application.

The preliminary amendment filed on 6/20/2005, adding new claims 23-34 and canceling claims 1-22 is acknowledged.

Election/Restriction

Applicant's election without traverse of Group I claims 23-24 and 32, drawn to an isolated polypeptide having cellobiohydrolases II activity and protein of SEQ ID NO: 2 in the communication filed on 12/4/2006 is acknowledged. Claims 25-31 and 33-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 23-24 and 32 are under consideration.

Priority

Acknowledgement is made of applicants claim for priority of provisional application 60/435,100 filed on 12/20/2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/20/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is considered by the examiner. The signed copy of IDS is enclosed herewith.

Drawings

There is no drawing with this application.

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Claim Objections

Claims 23 and 24 are objected to as encompassing non-elected subject matter. Appropriate correction is requested.

Claim 32 is objected to for twice recitation of "a microorganism belonging to the family Chaetomiaceae". Appropriate correction is requested.

Claim 32 is objected to for twice recitation of "a microorganism belonging to the genus *Aspergillus*". Appropriate correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23-24 and 32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 23-24 and 32 recite "A or The polypeptide", which reads on a naturally occurring polypeptide. Naturally occurring polypeptide is not patentable.

In the absence of the hand of man, naturally occurring nucleic acids and /or proteins are considered non-statutory subject matter. *Diamond and Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein". For examination purpose the claim is read as such.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claim 32 recites "pa microorganism" in line 12. The metes and bounds of the term "pa microorganism" are not clear to the Examiner. It is unclear to the Examiner as to what "pa" means in the context of a microorganism.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 32 is directed to a genus of polypeptides having cellobiohydrolase II activity, which is encoded by the cellobiohydrolase II encoding part of the nucleotide sequence present in several microorganisms recited in claim 32 including mutants and variants of SEQ ID NO: 2.

Claim 32 is drawn to an enzyme whose structure is not fully described in the specification. No information, beyond the characterization of a polypeptide having cellobiohydrolase II activity and the amino acid sequence of SEQ ID NO: 2 has been provided, which would indicate that applicants had possession of the claimed genus of any cellobiohydrolase present in any of said microorganisms. The specification does not contain any disclosure of the structure of all the mutants or variants of any polypeptide having

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cellobiohydrolase II activity within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including mutants and variants, which can have wide variety of structures. The specification discloses the structure of only a single representative species of the claimed genus i.e. SEQ ID NO: 2, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 23-24 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide having cellobiohydrolase II activity and the amino acid sequence of SEQ ID NO: 2 isolated from Chaetomiaceae thermophilum encoded by SEQ ID NO: 1, does not reasonably provide enablement for any polypeptide having cellobiohydrolase II activity isolated from any source or any polypeptide having 75% identical to SEQ ID NO: 2 or any polypeptide encoded by any polynucleotide sequence which is 75% sequence identity to SEQ ID NO: 1 or any fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make and use** the invention commensurate in scope with these claims.

Claims 23-24 and 32 are so broad as to encompass any polypeptide having cellobiohydrolase II activity isolated from any source or any polypeptide having 75% sequence

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identity to SEQ ID NO: 2 or any polypeptide encoded by any polynucleotide sequence which is 75% sequence identity to SEQ ID NO: 1 or any fragment thereof.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides including mutants and variants of SEQ ID NO: 2 broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one polypeptide having cellobiohydrolase II activity i.e. SEQ ID NO: 2.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any polypeptide having cellobiohydrolase II activity isolated from any source or any polypeptide having 75% sequence identity to SEQ ID NO: 2 or any polypeptide encoded by any

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polynucleotide sequence which is 75% sequence identity to SEQ ID NO: 1 or any fragment thereof because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting cellobiohydrolase activity; (B) the general tolerance of cellobiohydrolases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any polypeptide residue of SEQ ID NO: 2 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polypeptide having cellobiohydrolase II activity isolated from any source or any polypeptide having 75% sequence identity to SEQ ID NO: 2 or any polypeptide encoded by any polynucleotide sequence which is 75% sequence identity to SEQ ID NO: 1 or any fragment thereof. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any polypeptide having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-24 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hyashida et al. (Production and characteristics of avicel-digesting and non-avicel-digesting cellobiohydrolases from *Aspergillus ficum*, Appl Environ Microbiol. 1988 Jun; 54(6): 1523-1529). Instant claims drawn to a polypeptide comprising an amino acid sequence which has at least 75% identity with the polypeptide encoded by the cellobiohydrolase II enzyme encoding part of the nucleotide sequence present in *Chaetomium thermophilum* (claim 23, part b) having cellobiohydrolase II activity which is encoded by the cellobiohydrolase II encoding nucleotide sequence present in a microorganism selected from the group consisting of a microorganism belonging to the family Chaetomiaceae, a microorganism belonging to the genus *Myceliophthora*, a microorganism belonging to the species *Acremonium thermophilum*, a microorganism belonging to the family Chaetomiaceae, a microorganism belonging to the genus *Aspergillus*, a microorganism belonging to the family Chaetomiaceae, a microorganism belonging to the genus *Aspergillus*, a microorganism belonging to the Polyporales, a microorganism belonging to the Hymenochaetales, a microorganism belonging to the Pezizomycotina, a microorganism belonging to the species *Stilbella annulata*, and microorganism belonging to the species *Malbranchea cinnamomea*.

Hyashida et al. teach a cellobiohydrolase I and II from *Aspergillus ficum* and its isolation and purification. The protein of Hyashida et al. inherently possesses the activity of instant applicants protein because the function of the claimed enzyme and that of the reference is one and the same, Examiner takes the position that the protein disclosed in the reference inherently has the same function and characteristics as in the claimed enzyme of claims 23, 24 and 32 in the

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context of broad scope of the claims. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Therefore, Hyashida et al. anticipate claims 23-24 and 32 of the instant application.

Conclusion

Status of the claims:

Claims 23-34 are pending.

Claims 25-31 and 33-34 are withdrawn.

Claims 23-24 and 32 are rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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